



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

February 23, 2006

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 1839-83/ Detergent
Disinfectant
Pump Spray

DP Barcode: D324536

To: Velma Noble, PM 31/ **Zenobia Jones**
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist *Ian Blackwell*
Efficacy Evaluation Team
Product Science Branch
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Through: Karen Hicks, Team Leader *Karen J. Hicks*
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)
2/28/06

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Stephan Company

FORMULATION FROM LABEL:

| | |
|--|-----------------|
| <u>Active Ingredient(s):</u> | <u>% by wt.</u> |
| N-Alkyl dimethyl benzyl ammonium chlorides | 0.105 |
| N-Akyl dimethyl ethylbenzyl ammonium chlorides | 0.105 |
| <u>Other Ingredient(s):</u> | <u>99.790</u> |
| Total: | 100.000% |

- I BACKGROUND: The Stephan Company has submitted a dermal sensitization study to amend the acute toxicity requirements for their product, "Detergent Disinfectant Pump Spray". CTT/PSB conducted a review of this product on 2/22/05. The results of that review were:

| Study | MRID Number | Toxicity Category | Status |
|---------------------------|-------------|-------------------|------------|
| acute oral toxicity | 460146-03 | IV | Acceptable |
| acute dermal toxicity | 460146-01 | IV | Acceptable |
| acute inhalation toxicity | 464086-01 | IV | Acceptable |
| primary eye irritation | 460146-04 | III | Acceptable |
| primary skin irritation | 460146-02 | IV | Acceptable |
| dermal sensitization | 00131375 | Nonsensitizer | Acceptable |

For this submission, the company has submitted a relatively recent dermal sensitization study (12/3/2004) conducted on this registration product.

- II RECOMMENDATIONS: PSB findings are:

- 1 The dermal sensitization study is acceptable. This product is classified as a nonsensitizer.

For some reason, the report did not include the results of the scoring for irritation at the induction phase of testing. However, as the test material was induced at 100% concentration, the lack of induction scores can be overlooked in this case. However, the lack of induction scores has lead to study rejection in several other instances. Tox Monitor Laboratories should be made aware of this fact.

The acute toxicity-profile for Reg. No. 1839-83 is currently:

| Study | MRID Number | Toxicity Category | Status |
|---------------------------|-------------|-------------------|------------|
| acute oral toxicity | 460146-03 | IV | Acceptable |
| acute dermal toxicity | 460146-01 | IV | Acceptable |
| acute inhalation toxicity | 464086-01 | IV | Acceptable |
| primary eye irritation | 460146-04 | III | Acceptable |
| primary skin irritation | 460146-02 | IV | Acceptable |
| dermal sensitization | 466973-01 | Nonsensitizer | Acceptable |

III LABELING:

- 1 The signal word is "CAUTION".
- 2 The Precautionary Statements should state (this has not changed from the 2/22/5 review):

"Causes moderate eye irritation. Avoid contact with eye or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco."

- 3 The First Aid statements should state:

"If In Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing.
- Call a Poison Control Center or doctor for treatment advice."